

EXHIBIT G

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION**

INDIVIOR INC. *f/k/a* RECKITT
BENCKISER PHARMACEUTICALS
INC., and AQUESTIVE
THERAPEUTICS, INC. *f/k/a*
MONOSOL RX, LLC,

Plaintiffs,

v.

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Defendant.

Civil Action No. 5:15-cv-00350-D

**BIODELIVERY’S OBJECTIONS AND RESPONSES TO PLAINTIFFS’ FIRST SET OF
REQUESTS FOR PRODUCTION PURSUANT TO RULE 34 (NOS. 1-12)**

Pursuant to Federal Rules of Civil Procedure 34, Defendant BioDelivery Sciences International, Inc. (“BioDelivery”) objects and responds to Plaintiffs Aquestive Group, Inc. (“Aquestive”) and Indivior Inc. (“Indivior”; collectively, with Aquestive, “Plaintiffs”)’s First Set of Requests for Production Pursuant to Rule 34 (Nos. 1-12) dated June 1, 2021 as follows:

GENERAL OBJECTIONS

BioDelivery incorporates each of the following General Objections into its responses to each of Plaintiffs’ Requests for Production (“Request” or “Requests”), whether or not each such General Objection is expressly cited in BioDelivery’s response to a specific Request.

1. BioDelivery will make a reasonable effort to respond to Plaintiffs’ Requests, as BioDelivery understands and interprets those Requests. If Plaintiff subsequently asserts an

interpretation of any Request that differs from BioDelivery's interpretation, then BioDelivery reserves the right to supplement and amend its objections and responses.

2. BioDelivery objects to any Request to the extent that it is overly broad or unduly burdensome, or purports to impose upon BioDelivery any duty or obligation that is inconsistent with or in excess of those obligations that are imposed by the Federal Rules of Civil Procedure, the Court's local rules, or any other applicable rule. In particular, BioDelivery objects to any Request to the extent that it calls for information that is not relevant to any party's claims or defenses and is not proportional to the needs of the case.

3. BioDelivery objects to any Request to the extent that it purports to impose a duty or obligation to search for information and documents beyond a reasonable search of its files where information responsive to the Requests would reasonably be expected to be found.

4. BioDelivery objects to any Request that seeks information protected from disclosure by the attorney-client privilege, the attorney work product doctrine, the joint defense or common interest doctrine, or any other applicable privilege or immunity. The inadvertent disclosure of information protected from disclosure by any privilege or doctrine shall not constitute a waiver by BioDelivery of such objections or protections. To the extent that a Request calls for documents containing privileged information, BioDelivery will produce a privilege log at an appropriate time and subject to Plaintiffs also providing a privilege log.

5. BioDelivery objects to any Request that seeks "any," "each," or "all" documents or things as overly broad and unduly burdensome, except to the extent that such Request seeks reasonably narrow, non-cumulative information. BioDelivery notes that most of the Requests are objectionable insofar as they, at a minimum, seek "all documents" or "all communications."

Requests demanding the production of “all documents” are not proportional to the needs of this case. In response, and subject to its other objections, BioDelivery will produce responsive, representative documents that are non-cumulative, not protected from disclosure by the attorney-client privilege, work product doctrine, or any other applicable privilege or protection, and that can be reasonably identified after a reasonable search of its files where documents responsive to such a Request would reasonably be expected to be found.

6. BioDelivery objects to any Request that is premature and/or conflicts with any schedule for disclosure or expert opinions entered by the Court or provided for by the local rules.

7. BioDelivery objects to Plaintiffs’ “Definitions” and “Instructions” to the extent that they attempt to impose burdens and requirements upon BioDelivery that exceed or differ from the requirements of Rules 26 and 34 of the Federal Rules of Civil Procedure, the Court’s local rules, or any other applicable rule or court order.

8. BioDelivery objects to Plaintiffs’ definition of “infringe” and “infringement” to the extent that it purports to include infringement theories not alleged in this case.

9. BioDelivery objects to the use of any definition that serves to obfuscate what the Accused Products are.

10. BioDelivery objects to each Request to the extent that it seeks information that BioDelivery is under an obligation to a third party or a court order not to disclose, or is precluded from disclosing under legal obligations of any kind, including domestic or foreign privacy laws, U.S. agency regulations (e.g., regulations of the Department of Transportation and the TSA), and the like. BioDelivery will only produce responsive, non-privileged or otherwise protected

information in accordance with any applicable legal standards and after receiving approval from the relevant third parties and in accordance with the Protective Order entered in the above-captioned litigation.

11. BioDelivery objects to the Requests to the extent they are not limited to a reasonable time period.

12. BioDelivery's responses and objections to the Requests are made without waiver and with preservation of the following rights and privileges:

- a. all questions as to competency, relevance, materiality, privilege, and admissibility of the responses and the subject matter thereof for any purpose and in any further proceeding in this lawsuit (including trial) and in any other action or matter;
- b. the right to object to the use of any such responses or the subject matter thereof, on any ground in any further proceeding in this lawsuit (including trial) and in any other action or matter;
- c. the right to object on any ground at any time to a Request or request for further responses; and
- d. the right at any time to review, correct, add to, supplement, or clarify any of the responses contained herein.

13. BioDelivery objects to the Instructions to the extent they seek to impose unilateral parameters concerning the collection and production of electronically stored information (ESI) beyond those required by the Federal Rules of Civil Procedure and any applicable local rule or

court order.

14. All responses to the Requests are based on information presently known to BioDelivery after reasonable investigation. BioDelivery's objections as set forth herein are made without prejudice to BioDelivery's right to assert any additional or supplemental objections.

15. Any response in which BioDelivery agrees to produce responsive documents, whether or not made subject to objections, is not an admission or representation that any such document exists.

**SPECIFIC RESPONSES AND OBJECTIONS TO
REQUESTS FOR PRODUCTION OF DOCUMENTS**

REQUEST FOR PRODUCTION NO. 1:

All documents and things concerning Defendant's NDA, including the full and complete NDA, all documents and things submitted to the FDA in connection with Defendant's NDA, and supplements or amendments to Defendant's NDA, and all drafts of any of the above.

RESPONSE TO REQUEST NO. 1:

BioDelivery objects to this Request in purporting to seek production of information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the

needs of this case in demanding the production of “[a]ll documents and things concerning Defendant’s NDA...”

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search of its files and following entry of, and subject to the terms of, an agreed protective order in this matter.

REQUEST FOR PRODUCTION NO. 2:

All documents and things considered or relied upon by Defendant in preparation of Defendant’s NDA and any amendments or supplements thereof.

RESPONSE TO REQUEST NO. 2:

BioDelivery objects to this Request as seeking production of information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery’s highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things considered or relied upon by Defendant in preparation of Defendant’s NDA and any amendments or supplements thereof.” BioDelivery further objects to this Request as vague and ambiguous, in particular in demanding the production of “[a]ll documents and things considered or relied upon by Defendant”

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, an agreed protective order in this matter.

REQUEST FOR PRODUCTION NO. 3:

All documents and things concerning any correspondence or communication relating to Defendant's NDA and/or BUNAVAIL, including any and all correspondence or communications to or from the FDA concerning Defendant's NDA, including any and all NDA amendments and supplements.

RESPONSE TO REQUEST NO. 3:

BioDelivery objects to this Request as seeking information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things concerning any correspondence or communicating relating to Defendant's NDA and/or BUNAVAIL ...". Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are.

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the

extent any are located after a reasonable search and following entry of, and subject to the terms of, an agreed protective order in this matter.

REQUEST FOR PRODUCTION NO. 4:

All documents and things reflecting all components of BUNAVAIL, including all active ingredients and inactive ingredients or excipients, and including an identification of the purpose of each component and the amount of each component contained in BUNAVAIL.

RESPONSE TO REQUEST NO. 4:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things reflecting all components of BUNAVAIL ..." Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are.

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, an agreed protective order in this matter.

REQUEST FOR PRODUCTION NO. 5:

All documents and things concerning the manufacture or testing of BUNAVAIL without regard to whether such testing was reported to the FDA.

RESPONSE TO REQUEST NO. 5:

BioDelivery objects to this Request as seeking information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things concerning the manufacture or testing of BUNAVAIL ..." BioDelivery also objects to this Request as premature to the extent it purports to demand the production of expert discovery. BioDelivery further objects to this Request as seeking production of documents and things having no relevance to the claims and defenses in this matter, including in demanding production of documents and things reflecting "the manufacture ... of BUNAVAIL." Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are.

Subject to the foregoing General and specific objections, BioDelivery responds that it is willing to meet and confer to narrow the scope of this Request.

REQUEST FOR PRODUCTION NO. 6:

All documents and things reflecting the procedures and processes used to manufacture BUNAVAIL, including, but not limited to, a description of all mixing, casting, drying, and coating steps, and a description of any changes to those manufacturing procedures and processes starting from the date the FDA approved BDSI's NDA (i.e., June 6, 2014) through and including the present.

RESPONSE TO REQUEST NO. 6:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things reflecting the procedures and processes used to manufacture BUNAVAIL ..." Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are. BioDelivery further objects to this Request as seeking production of documents and things having no relevance to the claims and defenses in this matter, including in demanding production of documents and things reflecting "a description of all mixing, casting, ... and coating steps."

Subject to the foregoing General and specific objections, BioDelivery responds that it is willing to meet and confer to narrow the scope of this Request.

REQUEST FOR PRODUCTION NO. 7:

All documents and things concerning the formulation and manufacture of Defendant's BUNAVAIL products, including any and all work done by Defendant or done at the Defendant's instruction or for a Defendant's benefit by others, to develop the formulation, the amounts and proportions of all ingredients and materials used in the formulation, and all associated processing methods and manufacturing steps.

RESPONSE TO REQUEST NO. 7:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things concerning the formulation and manufacture of Defendant's BUNAVAIL products" Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are. BioDelivery further objects to this Request as seeking production of documents and things having no relevance to the claims and defenses in this matter, including in demanding production of documents and things reflecting "all associated processing methods and manufacturing steps."

Subject to the foregoing General and specific objections, BioDelivery responds that it is willing to meet and confer to narrow the scope of this Request.

REQUEST FOR PRODUCTION NO. 8:

All documents and things concerning the drying process for Defendant's BUNAVAIL products that Defendant considered, tested, evaluated, or proposed for submission to the FDA, or submitted to the FDA.

RESPONSE TO REQUEST NO. 8:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things concerning the drying process for Defendant's BUNAVAIL products that Defendant considered" Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are.

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, an agreed protective order in this matter.

REQUEST FOR PRODUCTION NO. 9:

All documents and things concerning testing, evaluation, or measurements conducted by or on behalf of BDSI related to the amount and distribution of active ingredients in Defendant's BUNAVAIL products, including, but not limited to testing, evaluations, or measurements of the amount and distribution of active ingredients in an individual dosage unit and/or the variation of the amount and distribution of active ingredients between individual dosage units.

RESPONSE TO REQUEST NO. 9:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things concerning testing, evaluation, or measurements conducted by or on behalf of BDSI related to the amount and distribution of active ingredients in Defendant's BUNAVAIL products ... " BioDelivery further objects to this Request as premature to the extent it purports to demand production of expert discovery or seeks to elicit BioDelivery's claim construction positions. Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are.

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the

extent any are located after a reasonable search and following entry of, and subject to the terms of, an agreed protective order in this matter.

REQUEST FOR PRODUCTION NO. 10:

All documents and things concerning methods, calculations, and analyses related to determining the amount and distribution of active ingredients, in any pharmaceutical film product created during the development of, or tested for the purpose of developing, Defendant's BUNAVAIL products.

RESPONSE TO REQUEST NO. 10:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things concerning methods, calculations, and analyses related to determining the amount and distribution of active ingredients, in any pharmaceutical film product created during the development of, or tested for the purpose of developing, Defendant's BUNAVAIL products." BioDelivery also objects to this Request as vague and ambiguous in seeking production of "[a]ll documents and things concerning ... any pharmaceutical film product created during the development of, or tested for the purpose of developing, Defendants' BUNAVAIL products." Further, BioDelivery objects to

this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are.

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, an agreed protective order in this matter.

REQUEST FOR PRODUCTION NO. 11:

All documents and things related to or referring to process flow specifications performed or investigated during production or development of Defendant's BUNAVAIL products, including ingredients, amounts, mixing, casting, drying steps and detailed diagrams and/or photographs of the apparatuses used in each step.

RESPONSE TO REQUEST NO. 11:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery's highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of "[a]ll documents and things related to or referring to process flow specifications performed or investigated during production or development of Defendant's BUNAVAIL products" BioDelivery further objects to this Request as demanding production of information irrelevant to the claims and defenses in this matter,

including in demanding production of documents and things “related to or referring to ... amounts, mixing, casting, ... steps and detailed diagrams and/or photographs of the apparatuses used in each step.” Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are.

Subject to the foregoing General and specific objections, BioDelivery responds that it is willing to meet and confer to narrow the scope of this Request.

REQUEST FOR PRODUCTION NO. 12:

All documents and things relating to Defendant’s assertions that Defendant’s BUNAVAIL product does not infringe and will not infringe the patents-in-suit, including all such information that Defendant contend support those positions or which tends to undermine or contradict such contentions.

RESPONSE TO REQUEST NO. 12:

BioDelivery objects to this Request as seeking the production of information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it demands the production of BioDelivery’s highly confidential information before the parties have agreed to the terms of a protective order, which agreement we expect to be reached shortly. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things relating to Defendant’s assertions that Defendant’s BUNAVAIL products does not infringe or will not infringe the patents-in-suit ... ” BioDelivery further objects to this Request as premature in purporting to demand production of expert discovery or seeking to elicit BioDelivery’s claim

construction positions. BioDelivery also objects to this Request as nonsensical in seeking production of information regarding the “patents-in-suit.” Further, BioDelivery objects to this Request to the extent that it uses a term whose definition serves to obfuscate what the Accused Products are. In addition, BioDelivery objects to this Request as premature because the inadequacies of Plaintiffs’ Preliminary Infringement Contentions served on June 21, 2021 prevent them serving their intended notice function. BioDelivery notes that Plaintiffs’ Preliminary Infringement Contentions served on June 21, 2021, are inadequate at least because they rely on the conflation of the BUNAVAIL individual film dosage units approved by the FDA with manufacturing precursors thereto; they rely on constructions of claim limitations inconsistent with those applied to gain allowance and/or avoid cancellation; they rely on conflation of different claim terms; they ignore claim limitations; they rely on recapture of disclaimed claim scope; they make the scope of the Asserted Claims unreasonably difficult to ascertain; and they are inconsistent with any objectively reasonable description of the BUNAVAIL individual film dosage units approved by the FDA.

Subject to these objections and the foregoing General Objections, and to the extent BioDelivery can understand this Request, after Plaintiffs disclose adequate infringement contentions—if they do so—and at an appropriate time consistent with the case schedule, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, an agreed protective order in this matter.

Dated: July 1, 2021

OF COUNSEL:

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*Local Civil Rule 83.1(d)
Counsel for Defendant
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CERTIFICATE OF SERVICE

I, certify that on July 1, 2021, I served this document on Plaintiffs, by emailing this document to Plaintiffs' counsel of record at the following e-mail addresses:

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